# **Complete Summary**

#### **GUIDELINE TITLE**

Emergency oral contraception.

# BIBLIOGRAPHIC SOURCE(S)

American College of Obstetricians and Gynecologists (ACOG). Emergency oral contraception. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2001 Mar. 8 p. (ACOG practice bulletin; no. 25). [48 references]

#### **GUIDELINE STATUS**

This is the current release of the guideline.

This guideline updates a previous version: Emergency oral contraception. Washington (DC): American College of Obstetricians and Gynecologists; 1996 Dec. 8 p. (ACOG practice patterns; no. 3).

#### **COMPLETE SUMMARY CONTENT**

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis RECOMMENDATIONS

EVIDENCE SUPPORTING THE RECOMMENDATIONS

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS CONTRAINDICATIONS

QUALIFYING STATEMENTS

IMPLEMENTATION OF THE GUIDELINE

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY

## **SCOPE**

# DISEASE/CONDITION(S)

Unintended pregnancy resulting from unprotected sexual intercourse including sexual assault

### **GUIDELINE CATEGORY**

Counseling Management

#### CLINICAL SPECIALTY

Obstetrics and Gynecology Pharmacology

#### INTENDED USERS

Physicians

## GUIDELINE OBJECTIVE(S)

- To aid practitioners in making decisions about appropriate obstetric and gynecologic care
- To present evidence regarding the safety, efficacy, risks, and benefits of the use of oral contraceptives for emergency contraception

## TARGET POPULATION

Women who had unprotected sexual intercourse within the previous 72 hours

# INTERVENTIONS AND PRACTICES CONSIDERED

- 1. Emergency oral contraception including combination method consisting of ethinyl estradiol and levonorgestrel or norgestrel and progestin-only method consisting of levonorgestrel. Refer to Table 1 in the original guideline document for detailed information on the formulation and dosage of common oral contraceptives used as emergency contraception.
- 2. Antiemetic agent to be taken 1 hour before the first dose of combination oralcontraceptive method
- 3. Counseling patients regarding effective contraceptive methods, sexually transmitted diseases, and safe sex practices at the time emergency contraception is prescribed
- 4. Offering patients an advance prescription for emergency contraception during a routine gynecologic visit
- 5. Evaluating patients for pregnancy if menses have not begun within 21 days following emergency contraception treatment

#### MAJOR OUTCOMES CONSIDERED

The failure rate of emergency contraception with combination method and progestin-only method

#### METHODOLOGY

# METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

#### DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The MEDLINE database, the Cochrane Library, and American College of Obstetricians and Gynecologists' (ACOG's) own internal resources and documents were used to conduct a literature search to locate relevant articles published between January 1985 and June 2000. The search was restricted to articles published in the English language. Priority was given to articles reporting results of original research, although review articles and commentaries also were consulted. Abstracts of research presented at symposia and scientific conferences were not considered adequate for inclusion in this document.

Guidelines published by organizations or institutions such as the National Institutes of Health and the American College of Obstetricians and Gynecologists were reviewed, and additional studies were located by reviewing bibliographies of identified articles.

#### NUMBER OF SOURCE DOCUMENTS

Not stated

# METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

#### RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Studies were reviewed and evaluated for quality according to the method outlined by the U.S. Preventive Services Task Force:

- I Evidence obtained from at least one properly designed randomized controlled trial
- II-1 Evidence obtained from well-designed controlled trials without randomization
- II-2 Evidence obtained from well-designed cohort or case—control analytic studies, preferably from more than one center or research group
- II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.
- $\ensuremath{\mathsf{III}}$  Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

#### METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses Systematic Review

#### DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

#### METHODS USED TO FORMULATE THE RECOMMENDATIONS

**Expert Consensus** 

# DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Analysis of available evidence was given priority in formulating recommendations. When reliable research was not available, expert opinions from obstetriciangynecologists were used. See also the "Rating Scheme for the Strength of Recommendations" field regarding Grade C recommendations.

#### RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Based on the highest level of evidence found in the data, recommendations are provided and graded according to the following categories:

Level A — Recommendations are based on good and consistent scientific evidence.

Level B — Recommendations are based on limited or inconsistent scientific evidence.

Level C — Recommendations are based primarily on consensus and expert opinion.

# **COST ANALYSIS**

The purpose of emergency contraception is to avoid unintended pregnancy. Many of these pregnancies also are unwanted. Emergency contraception will prevent most pregnancies resulting from a single act of unprotected intercourse. Thus, the treatment costs of any subsequent induced abortions, spontaneous abortions, ectopic pregnancies, and pregnancies carried to fetal viability will be avoided.

#### METHOD OF GUIDELINE VALIDATION

Internal Peer Review

# DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Practice Bulletins are validated by two internal clinical review panels composed of practicing obstetrician-gynecologists, generalists and subspecialists. The final guidelines are also reviewed and approved by the American College of Obstetricians and Gynecologists (ACOG) Executive Board.

#### RECOMMENDATIONS

#### MAJOR RECOMMENDATIONS

The grades of evidence (I-III) and levels of recommendations (A-C) are defined at the end of "Major Recommendations" field.

The following recommendations are based on good and consistent scientific evidence (Level A):

- Combination or progestin-only oral contraceptives for emergency contraception should be offered to women who have had unprotected sexual intercourse within 72 hours of intercourse.
- Because the progestin-only method produces less nausea and may be more
  effective than the combination oral-contraceptive method, this regimen
  should be strongly considered.
- To minimize nausea and vomiting with combination oral-contraceptive products, an antiemetic agent should be prescribed and the patient should take it 1 hour before the first oral contraceptive dose.
- During a routine gynecologic visit, physicians who wish to increase the availability and use of emergency contraception may offer patients an advance prescription for emergency contraception.

The following recommendations are based on limited or inconsistent scientific evidence (Level B):

- If possible, emergency contraception should be used within the first 24 hours after unprotected intercourse because efficacy may be greatest if used within 24 hours after exposure.
- Patients should be evaluated for pregnancy if menses have not begun within 21 days following emergency contraception treatment.

The following recommendations are based primarily on consensus and expert opinion (Level C):

- Counseling regarding effective contraceptive methods, sexually transmitted diseases, and safe sex practices should be undertaken, when feasible, at the time emergency contraception is prescribed.
- Data are insufficient to evaluate the effectiveness of emergency contraception treatment when initiated more than 72 hours and up to 120 hours after a single act of unprotected sexual intercourse. Therefore, the risk and benefits of treatment should be weighed on a case-by-case basis.
- No data specifically examine the risk of using hormonal methods of emergency contraception among women with contraindications to the use of conventional oral-contraceptive preparations; nevertheless, emergency contraception may be offered to such women.
- In a woman with a history of idiopathic thrombosis, the progestin-only regimen may be preferred.

#### Definitions:

#### Grades of Evidence

- I Evidence obtained from at least one properly designed randomized controlled trial
- II-1 Evidence obtained from well-designed controlled trials without randomization
- II-2 Evidence obtained from well-designed cohort or case—control analytic studies, preferably from more than one center or research group
- II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.
- III Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

#### Levels of Recommendation

- Level A Recommendations are based on good and consistent scientific evidence.
- Level B Recommendations are based on limited or inconsistent scientific evidence.
- Level C Recommendations are based primarily on consensus and expert opinion.

#### CLINICAL ALGORITHM(S)

None provided

#### EVIDENCE SUPPORTING THE RECOMMENDATIONS

#### TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

# BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

#### POTENTIAL BENEFITS

## **Overall Benefits**

Appropriate use of emergency oral contraception, improved physician familiarity with and public awareness of the method, and prompt availability of emergency oral contraception methods

# Specific Benefits

Two studies have evaluated the advance provision of emergency contraception at the time of a routine gynecologic visit to women of reproductive age as a means of increasing availability and use of the treatment. Both studies showed that women given emergency contraception in advance were significantly more likely to use it than women who were simply educated about emergency contraception and how to obtain it.

#### POTENTIAL HARMS

## Adverse Effects of Contraceptive Agents

- Common adverse effects of combination oral contraceptives for emergency contraception are nausea, vomiting, and breast tenderness
- The frequency of nausea, vomiting, dizziness, and fatigue with the progestinonly method is significantly less compared with the combination method.
- Norgestrel was associated with higher rates of side effects when compared with products containing levonorgestrel.

#### CONTRAINDICATIONS

#### **CONTRAINDICATIONS**

Emergency oral contraception should not be used in a patient with a known or suspected pregnancy, hypersensitivity to any component of the product, or undiagnosed abnormal genital bleeding.

# QUALIFYING STATEMENTS

#### QUALIFYING STATEMENTS

These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.

# IMPLEMENTATION OF THE GUIDELINE

# DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

# INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

**IOM CARE NEED** 

Staying Healthy

#### IOM DOMAIN

Effectiveness
Patient-centeredness
Timeliness

# IDENTIFYING INFORMATION AND AVAILABILITY

# BIBLIOGRAPHIC SOURCE(S)

American College of Obstetricians and Gynecologists (ACOG). Emergency oral contraception. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2001 Mar. 8 p. (ACOG practice bulletin; no. 25). [48 references]

### **ADAPTATION**

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2001 Mar

GUIDELINE DEVELOPER(S)

American College of Obstetricians and Gynecologists - Medical Specialty Society

SOURCE(S) OF FUNDING

American College of Obstetricians and Gynecologists (ACOG)

**GUI DELI NE COMMITTEE** 

American College of Obstetricians and Gynecologists (ACOG) Committee on Practice Bulletins-Gynecology

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

**GUI DELI NE STATUS** 

This is the current release of the guideline.

This guideline updates a previous version: Emergency oral contraception. Washington (DC): American College of Obstetricians and Gynecologists; 1996 Dec. 8 p. (ACOG practice patterns; no. 3).

#### GUIDELINE AVAILABILITY

Electronic copies: None available

Print copies: Available for purchase from the American College of Obstetricians and Gynecologists (ACOG) Distribution Center, PO Box 4500, Kearneysville, WV 25430-4500; telephone, 800-762-2264, ext. 192; e-mail: <a href="mailto:sales@acog.org">sales@acog.org</a>. The ACOG Bookstore is available online at the <a href="mailto:ACOG Web site">ACOG Web site</a>.

#### AVAILABILITY OF COMPANION DOCUMENTS

None available

#### PATIENT RESOURCES

None available

#### NGC STATUS

This NGC summary was completed by ECRI on September 22, 2004. The information was verified by the guideline developer on December 9, 2004.

# **COPYRIGHT STATEMENT**

This NGC summary is based on the original guideline, which is subject to the guideline developer's copyright restrictions.

© 1998-2005 National Guideline Clearinghouse

Date Modified: 2/14/2005



